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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/669,705	09/25/2003	Hao Chen	6695.0004-01	6343

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CALIPER LIFE SCIENCES, INC.  
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EXAMINER

WHALEY, PABLO S

ART UNIT	PAPER NUMBER
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1631

MAIL DATE	DELIVERY MODE
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07/09/2007

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

# Office Action Summary

Application No.

10/669,705

Applicant(s)

CHEN, HAO

Examiner

Pablo Whaley

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 01 May 2007 and 08 January 2007.
- 2a) ☒ This action is FINAL. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-8 and 38-41 is/are pending in the application.
- 4a) Of the above claim(s) 39 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-8, 38, 40 and 41 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

## DETAILED ACTION

Applicants' remarks, filed 05/01/2007 and 01/08/2007, have been fully considered. The following rejections and/or objections are maintained, newly applied, or withdrawn for the reasons set forth below. They constitute the complete set presently being applied to the instant application.

### *CLAIMS UNDER EXAMINATION*

Claims 38-41 are newly added. Claims 9-37 have been cancelled. Applicant's election without traverse of Group I (Claims 1-8) in the reply filed on 04/14/2006, and election without traverse of Specie A ("toxicity" as recited in instant claim 5) is reiterated. Claim 39 recites a non-elected species of therapeutic effects. Accordingly, claim 39 is withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention or species, there being no allowable generic or linking claim. Claims 1-8 and 38, 40, and 41 are herein under examination as they read on the elected species.

### *ABSTRACT*

The amended abstract filed 01/08/2007 is acceptable.

### *PRIORITY*

Priority Applicant's claim for the benefit of a prior-filed application under 35 U.S.C. 119(e) or under 35 U.S.C. 120, 121, or 365(c) is acknowledged. Applicant has not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. 119(e) or 120

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as follows: The later-filed application must be an application for a patent for an invention which is also disclosed in the prior application (the parent or original nonprovisional application or provisional application). The disclosure of the invention in the parent application and in the later-filed application must be sufficient to comply with the requirements of the first paragraph of 35 U.S.C. 112. See *Transco Products, Inc. v. Performance Contracting, Inc.*, 38 F.3d 551, 32 USPQ2d 1077 (Fed. Cir. 1994). The instant application is a CIP of 10/105,407 and 09/558,232, and has been amended to recite new limitations directed to "reverse partitioning" (amended claim 3). The disclosure of the prior-filed applications, 10/105,407 and 09/558,232, fails to provide adequate support or enablement for this limitation in the manner provided by the first paragraph of 35 U.S.C. 112 for one or more claims of this application. Priority is therefore only granted to provisional application 60/366,576, filed 3/25/2002.

#### **CLAIM REJECTIONS - 35 USC § 112, 2<sup>nd</sup> Paragraph**

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 3 and 7 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. *These rejections are necessitated by amendment.*

Claim 3 now recites the limitation "reverse partitioning." As the specification does not define or fully and completely describe this term, it is unclear as to the metes and bounds intended by applicant. Clarification is requested.

Claim 7 now recites the limitation "the there are multiple targets." This limitation is unintelligible. The Examiner believes there is a grammatical error. Clarification is requested.

**CLAIM REJECTIONS - 35 USC § 112 1<sup>st</sup> Paragraph**

Claim 3 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claims contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor, at the time the application was filed, had possession of the claimed invention. This is a NEW MATTER rejection.

Claim 3 has been amended to recite "reverse partitioning." Applicant's response, while very detailed with regards to amended claim 1, did not point to support for this newly recited limitation. This limitation is not taught in the specification and is not present within the scope of the original claims as filed. Accordingly, the above claim is rejected for reciting new matter. *This rejection is necessitated by amendment.*

**CLAIM REJECTIONS - 35 USC § 101**

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 1-8 remain rejected and newly added claims 38, 40, and 41 are rejected under 35 U.S.C. 101 because these claims are drawn to non-statutory subject matter.

Applicant's arguments, filed 01/08/2007, that the instantly rejected claims are now statutory under the assertion that they now produce a practical application are not persuasive for the following reasons. According to the revised Guidelines, a claimed invention directed to a statutory process must provide: (1) a practical application by physical transformation (i.e. reduction of an article to a different state or thing), or (2) a practical application that produces a concrete, tangible, and useful result. The revised Guidelines also state that the focus is "not on whether the steps taken to achieve a particular result are useful, tangible, and concrete, but rather on whether the final result achieved by the claimed invention is useful, tangible, and concrete."

In view of the revised Guidelines, and in view of the amendment to claim 1, the Examiner maintains that the claimed method does recite a physical transformation of matter, as all of the claimed method steps may conceivably be practice inside of a computer. Where a claimed method does not result in a physical transformation of matter, it may be statutory where it recites a result that is concrete (i.e. reproducible), tangible (i.e. real world), and useful result (i.e. a specific and substantial). However, claim 1 results "identifying" candidate compounds with descriptors, and thus does not recite a tangible result such that it is useful to one skilled in the art. For these reasons, this rejection is maintained.

This rejection could be overcome by amending the claims to recite a "tangible" (i.e. real-world result). For example, in view of the revised guidelines, applicant would likely overcome this rejection by amending the claims to recite: (1) an active method step that provides a physical transformation of matter (e.g. assay); or (2) a method step that results in a claimed method is communicated to a user (i.e. real-world result), graphically displayed, or output (e.g. to a user, to a memory, or to another computer); For an updated discussion of statutory considerations, see the revised Guidelines for Patent Eligible Subject Matter in the MPEP 2106,

### CLAIM REJECTIONS - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C.102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-8 were rejected under 35 U.S.C. 102 (b) as being anticipated by Lawrence et al. (Proteins: Structure, Function, and Genetics, 1992, 12, p.31-41). This rejection is hereby withdrawn. Applicant's arguments, filed 01/08/2007, that Lawrence et al. fails to teach a "full-rank" database of interactions, or using a database to monitor activity between two or more molecular targets are persuasive.

Claims 1, 2, 4-7, and 40 are rejected under 35 U.S.C. 102 (b) as being anticipated by Nilakantan et al. (J. Chem. Inf. Comput. Sci., 1993, Vol. 33, p.79-85). *This rejection is necessitated by amendment.*

Nilakantan et al. teach a drug discovery method for rapid characterization of molecular shapes [Abstract]. Nilakantan et al. teach method steps that anticipate those of the instant claims as follows: a process wherein a template molecule is compared to a database of candidate molecules using numerical descriptors (i.e. triplets) derived from structural features of the molecular targets to identify compound descriptors (i.e. triplet signature) associated with

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desired interactions (i.e. thresholds) [p.79, Col. 2, Methods] and [Fig. 1], as in claims 1 and 5. Candidate compounds are ranked and represented in terms of descriptors [Fig. 3 and 4], as in claims 1 and 5. Template compounds include *netropsin* [Fig. 4], which is a well-known antibiotic, antitumor, and antiviral agent and thus is inherently associated with 'disease states' (e.g. cancer and viral infections). A large 3-D database of known compounds for testing [p.80, Col. 1, ¶ 1] and [p.84, Appendix II], as in claims 2 and 6. Descriptors are found by calculating distances of a triangle (i.e. 2-D planar figure) [p.84, Appendix I], which is broadly interpreted as 2-D bond length descriptors as in claims 4 and 40. Comparison of data includes identifying compound descriptors above a threshold (i.e. desired activity) and below a threshold (i.e. undesired activity) [Fig. 1], which equates to the step of "analyzing" as in claim 5.

### Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).



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Claims 1-8, 38, 40, and 41 are rejected under 35 U.S.C. 103(a) as being made obvious by Nilakantan et al. (J. Chem. Inf. Comput. Sci., 1993, Vol. 33, p.79-85), as applied to claims 1, 2, 4-7, and 40, above, in view of Chen et al. (J. Chem. Inf. Comput. Sci., 1998, Vol. 38, p.1054-1062) and Grass et al. (US 6,542,858; filed May 26, 1999). *This rejection is necessitated by amendment.*

Nilakantan et al. teach a drug discovery method for rapid characterization of molecular shapes [Abstract], as set forth above and applied to claims 1, 2, 4-7, and 40.

Nilakantan et al. do not specifically teach the limitation of "reverse partitioning" as in claims 3 and 41, or undesired effects as recited in claims 8 and 38.

Chen et al. teach a method of drug discovery and development based on recursive partitioning analysis of large structure-activity data sets using 3-D descriptors [Abstract], as in claims 3 and 41. Chen et al. also provide a database comprising active and inactive 3-D compound conformations [p.1055, Col. 1, ¶ 2] and data sets of over 2,000,000 descriptors for analysis of large chemical data [Abstract], wherein descriptors include atomic distance between two molecules [p.1055, Col. 2, ¶ 2].

Grass et al. teach a pharmacokinetic-based method and selection tool (PK tool) drug for predicting the absorption of administered compounds of interest [Abstract], [Fig. 1, 3, 4, and 9]. Output of the method and PK tool can be utilized to profile or rank compounds by a selected absorption parameter for toxicity [Col. 12, ¶ 1], as in claims 8 and 38.

Thus it would have been obvious to someone of ordinary skill in the art at the time of the instant invention to practice the method of Nilakantan et al. using recursive partitioning analysis taught by Chen et al., and ranking of candidates for toxicity as taught by Grass et al., as recursive partitioning (RP) is a well known statistical method for analyzing very large data sets

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[Chen et al., Abstract]. One of ordinary skill in the art would have been motivated to combine the above teachings in view of the growing need to develop 3-D pharmacophores from large data sets to guide database screening, chemical library design, and lead optimization [Chen et al., Abstract], resulting in the practice of the instant claimed invention. One of skill in the art would have had a reasonable expectation of successfully combining the above teachings as all are directed to large data sets and structure-activity relationships of compounds.

### CONCLUSION

No claims are allowed.

Accordingly, THIS ACTION IS MADE FINAL. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Pablo Whaley whose telephone number is (571)272-4425. The examiner can normally be reached on 9:30am - 6pm.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla can be reached at 571-272-0735. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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